

§ 868.1

868.5470	Hyperbaric chamber.
868.5530	Flexible laryngoscope.
868.5540	Rigid laryngoscope.
868.5550	Anesthetic gas mask.
868.5560	Gas mask head strap.
868.5570	Nonrebreathing mask.
868.5580	Oxygen mask.
868.5590	Scavenging mask.
868.5600	Venturi mask.
868.5610	Membrane lung for long-term pulmonary support.
868.5620	Breathing mouthpiece.
868.5630	Nebulizer.
868.5640	Medicinal nonventilatory nebulizer (atomizer).
868.5650	Esophageal obturator.
868.5655	Portable liquid oxygen unit.
868.5665	Powered percussor.
868.5675	Rebreathing device.
868.5690	Incentive spirometer.
868.5700	Nonpowered oxygen tent.
868.5710	Electrically powered oxygen tent.
868.5720	Bronchial tube.
868.5730	Tracheal tube.
868.5740	Tracheal/bronchial differential ventilation tube.
868.5750	Inflatable tracheal tube cuff.
868.5760	Cuff spreader.
868.5770	Tracheal tube fixation device.
868.5780	Tube introduction forceps.
868.5790	Tracheal tube stylet.
868.5795	Tracheal tube cleaning brush.
868.5800	Tracheostomy tube and tube cuff.
868.5810	Airway connector.
868.5820	Dental protector.
868.5830	Autotransfusion apparatus.
868.5860	Pressure tubing and accessories.
868.5870	Nonrebreathing valve.
868.5880	Anesthetic vaporizer.
868.5895	Continuous ventilator.
868.5905	Noncontinuous ventilator (IPPB).
868.5915	Manual emergency ventilator.
868.5925	Powered emergency ventilator.
868.5935	External negative pressure ventilator.
868.5955	Intermittent mandatory ventilation attachment.
868.5965	Positive end expiratory pressure breathing attachment.
868.5975	Ventilator tubing.
868.5995	Tee drain (water trap).

Subpart G—Miscellaneous

868.6100	Anesthetic cabinet, table, or tray.
868.6175	Cardiopulmonary emergency cart.
868.6225	Nose clip.
868.6250	Portable air compressor.
868.6400	Calibration gas.
868.6700	Anesthesia stool.
868.6810	Tracheobronchial suction catheter.
868.6820	Patient position support.
868.6885	Medical gas yoke assembly.

AUTHORITY: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

SOURCE: 47 FR 31142, July 16, 1982, unless otherwise noted.

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EDITORIAL NOTE: Nomenclature changes to part 868 appear at 73 FR 35341, June 23, 2008.

Subpart A—General Provisions

§ 868.1 Scope.

(a) This part sets forth the classification of anesthesiology devices intended for human use that are in commercial distribution.

(b) The identification of a device in a regulation in this part is not a precise description of every device that is, or will be, subject to the regulation. A manufacturer who submits a premarket notification submission for a device under part 807 may not show merely that the device is accurately described by the section title and identification provisions of a regulation in this part, but shall state why the device is substantially equivalent to other devices, as required by § 807.87.

(c) To avoid duplicative listings, an anesthesiology device that has two or more types of uses (e.g., used both as a diagnostic device and as a therapeutic device) is listed only in one subpart.

(d) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21, unless otherwise noted.

(e) Guidance documents referenced in this part are available on the Internet at <http://www.fda.gov/cdrh/guidance.html>.

[52 FR 17734, May 11, 1987, as amended at 67 FR 76681, Dec. 13, 2002]

§ 868.3 Effective dates of requirement for premarket approval.

A device included in this part that is classified into class III (premarket approval) shall not be commercially distributed after the date shown in the regulation classifying the device unless the manufacturer has an approval under section 515 of the act (unless an exemption has been granted under section 520(g)(2) of the act). An approval under section 515 of the act consists of FDA's issuance of an order approving an application for premarket approval (PMA) for the device or declaring completed a product development protocol (PDP) for the device.

(a) Before FDA requires that a device commercially distributed before the enactment date of the amendments, or

a device that has been found substantially equivalent to such a device, has an approval under section 515 of the act FDA must promulgate a regulation under section 515(b) of the act requiring such approval, except as provided in paragraph (b) of this section. Such a regulation under section 515(b) of the act shall not be effective during the grace period ending on the 90th day after its promulgation or on the last day of the 30th full calendar month after the regulation that classifies the device into class III is effective, whichever is later. See section 501(f)(2)(B) of the act. Accordingly, unless an effective date of the requirement for premarket approval is shown in the regulation for a device classified into class III in this part, the device may be commercially distributed without FDA's issuance of an order approving a PMA or declaring completed a PDP for the device. If FDA promulgates a regulation under section 515(b) of the act requiring premarket approval for a device, section 501(f)(1)(A) of the act applies to the device.

(b) Any new, not substantially equivalent, device introduced into commercial distribution on or after May 28, 1976, including a device formerly marketed that has been substantially altered, is classified by statute (section 513(f) of the act) into class III without any grace period and FDA must have issued an order approving a PMA or declaring completed a PDP for the device before the device is commercially distributed unless it is reclassified. If FDA knows that a device being commercially distributed may be a "new" device as defined in this section because of any new intended use or other reasons, FDA may codify the statutory classification of the device into class III for such new use. Accordingly, the regulation for such a class III device states that as of the enactment date of the amendments, May 28, 1976, the device must have an approval under section 515 of the act before commercial distribution.

[52 FR 17734, May 11, 1987]

§ 868.9 Limitations of exemptions from section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act).

The exemption from the requirement of premarket notification (section 510(k) of the act) for a generic type of class I or II device is only to the extent that the device has existing or reasonably foreseeable characteristics of commercially distributed devices within that generic type or, in the case of in vitro diagnostic devices, only to the extent that misdiagnosis as a result of using the device would not be associated with high morbidity or mortality. Accordingly, manufacturers of any commercially distributed class I or II device for which FDA has granted an exemption from the requirement of premarket notification must still submit a premarket notification to FDA before introducing or delivering for introduction into interstate commerce for commercial distribution the device when:

(a) The device is intended for a use different from the intended use of a legally marketed device in that generic type of device; e.g., the device is intended for a different medical purpose, or the device is intended for lay use where the former intended use was by health care professionals only;

(b) The modified device operates using a different fundamental scientific technology than a legally marketed device in that generic type of device; e.g., a surgical instrument cuts tissue with a laser beam rather than with a sharpened metal blade, or an in vitro diagnostic device detects or identifies infectious agents by using deoxyribonucleic acid (DNA) probe or nucleic acid hybridization technology rather than culture or immunoassay technology; or

(c) The device is an in vitro device that is intended:

(1) For use in the diagnosis, monitoring, or screening of neoplastic diseases with the exception of immunohistochemical devices;

(2) For use in screening or diagnosis of familial or acquired genetic disorders, including inborn errors of metabolism;

(3) For measuring an analyte that serves as a surrogate marker for screening, diagnosis, or monitoring